denotes change in current criteria
denotes new criteria

PCSK9 inhibitors- Repatha and Praluent

REPATHA *is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated for:*

- ***Atherosclerotic cardiovascular disease, primary prevention:*** *Adjunct to diet, alone or in combination with other lipid-lowering therapies (eg, maximally tolerated statin), for the treatment of adults with primary hyperlipidemia to reduce low-density lipoprotein-cholesterol (LDL-C).*
- ***Atherosclerotic cardiovascular disease, secondary prevention:*** *To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.* ***Note:*** *Use in combination with an optimized regimen of lipid-lowering therapy (eg, high-intensity statin).*
- ***Familial hypercholesterolemia, heterozygous:*** *Adjunct to diet, alone or in combination with other lipid-lowering therapies (eg, maximally tolerated statin) for the treatment of adults to reduce LDL-C; adjunct to diet and other lipid-lowering therapies for the treatment of pediatric patients ≥10 years of age to reduce LDL-C.*
- ***Familial hypercholesterolemia, homozygous:*** *Adjunct to other lipid-lowering therapies in pediatric patients ≥10 years of age and adults for the treatment of patients with homozygous familial hypercholesterolemia who require additional lowering of LDL-C.*

PRALUENT *is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated for:*

- ***Homozygous familial hypercholesterolemia:*** *Adjunct to other low-density lipoprotein cholesterol (LDL-C) lowering therapies in adults with homozygous familial hypercholesterolemia to reduce LDL-C.*
- ***Hyperlipidemia, primary:*** *Adjunct to diet, alone or in combination with other LDL-C lowering therapies in adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce LDL-C.*
- ***Secondary prevention of cardiovascular events:*** *To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.*

CRITERIA FOR APPROVAL

1) Patient must meet all age and indication restrictions imposed by the current FDA-approved label; **AND**

2) Documentation must be submitted indicating that the patient failed to reach goal LDL-C ~~< 70 mg/dL~~ after an 8-week trial of either **atorvastatin 40 - 80 mg ~~+ ezetimibe~~** OR **rosuvastatin 20 - 40 mg ~~+ ezetimibe~~.** Note: If the patient failed to tolerate the first statin~~/ezetimibe combination~~, then they must be trialed on the second statin ~~combination~~ for 8-weeks or until intolerance occurs.

Initial approval will be for 90 days.

Additional coverage may be granted with documentation of efficacy supported by at least a 40% LDL-C reduction from pre-treatment level. Maintenance therapy may be requested by any willing prescriber.

denotes change in current criteria
denotes new criteria

Vraylar

Current criteria:

***** Vraylar may be authorized for the indication of Bipolar Depression only after failure of a 30-day trial of Latuda and a 30-day trial of either quetiapine OR a combination of olanzapine + fluoxetine. All other indications require class criteria to be followed.

Proposed criteria:

~~***** Vraylar may be authorized for the indication of Bipolar Depression only after failure of a 30-day trial of Latuda and a 30-day trial of either quetiapine OR a combination of olanzapine + fluoxetine. All other indications require class criteria to be followed.~~

***** Vraylar may be authorized for the indication of major depressive disorder only after a 30-day trial and failure of 2 two preferred antidepressants. For all other indications a 30-day trial and failure of one preferred antipsychotic is required.

denotes change in current criteria
denotes new criteria

Tezspire (tezepelumab-ekko) injection

TEZSPIRE is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

Limitations of Use: Not for relief of acute bronchospasm or status asthmaticus

CRITERIA FOR APPROVAL:

1. The patient must have a diagnosis of severe asthma that is uncontrolled or inadequately controlled as demonstrated by experiencing at least one of the following within the past year: ≥ 2 exacerbations requiring oral or injectable corticosteroid treatment; OR ≥ 1 exacerbation resulting in hospitalization or emergency medical care visit; **AND**

2. Must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist; **AND**

3. The patient must be within the age range as recommended by the FDA label and indication; **AND**

4. The patient must have documented adherence to a therapeutic regimen consisting of a LABA + high dose ICS therapy in the last 90 days**; AND**

5. For patients with an eosinophilic phenotype documentation must be supplied indicating one of the following:

   a. A positive sputum test for eosinophilic phenotype asthma with sputum eosinophil level ≥ 3%; OR
   b. Asthma with eosinophilic phenotype with blood eosinophil count greater than or equal to 150 cells/mcL within the past 6 weeks or blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months; OR
   c. Claims data that reflect a continual reliance on oral corticosteroid therapy in the last 90 days.

Initial approval of Tezspire for asthma will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on the prescribed therapeutic regimen.

denotes change in current criteria
denotes new criteria

Ingrezza

INGREZZA is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia and for the treatment of adults with chorea associated with Huntington's disease.

Initial* Prior Authorization Criteria:

- The patient must be within the age range as recommended by the FDA label; **AND**
- Patient must not be taking an MAOI (at least 14-days post-therapy), reserpine (must be >20 days post therapy) or any other concurrent VMAT2 inhibitor; **AND**
- Prescriber must provide a brief description of the medical necessity of therapy by documenting all target symptoms and their impact on the patient's function and activities of daily living; **AND**

The following indication-specific criteria also apply:

I. Treatment of Chorea associated with Huntington's Disease:

1. Request must come from the treating neurologist; **AND**
2. Patient must have been evaluated and found not to be suicidal or have untreated/undertreated depression; **AND**
3. All previous therapies must be documented along with their relative benefit. Unless contraindicated, the patient must have a documented 90-day trial, which resulted in intolerance or inadequate treatment response, to **Xenazine (tetrabenazine)**.

II. Treatment of Tardive Dyskinesia (TD):

1. Request must come from the treating neurologist or psychiatrist; **AND**
2. Patient must provide a documented clinical diagnosis of tardive dyskinesia meeting DSM-V criteria including:
    a. Involuntary athetoid or choreiform movements
    b. History of treatment with a dopamine receptor blocking agent (DRBA) such as an antipsychotic or metoclopramide
    c. Symptom duration lasting at least 8 weeks; **AND**
3. Prescriber must submit the results of an Abnormal Involuntary Movement Scale (AIMS) exam with every request for prior authorization of Ingrezza; **AND**
4. Prescriber must submit documentation of all other therapies attempted and their associated benefit **(including relevant AIMS scores)**.

denotes change in current criteria
denotes new criteria

***Initial prior-authorization will be for 90 days.**
Continuation of coverage requires clinically significant improvement in symptoms as compared to that seen using previous therapy.

denotes change in current criteria
denotes new criteria

Antiemetics- combination products

Diclegis

~~*DICLEGIS is a fixed dose combination drug product of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.*~~

~~**Prior authorization requests for Diclegis may be approved if the following criteria are met:**~~

1. ~~Diagnosis of nausea and vomiting associated with pregnancy;~~ ~~**AND**~~

2. ~~Failure of conservative therapy for nausea and vomiting* (please document all previous therapies);~~
   ~~*An algorithm containing recommended alternative management strategies for nausea and vomiting of pregnancy (NVP) may be found at the end of this document.~~
   ~~**AND**~~

3. ~~Failure of a seven (7) day trial of combination therapy consisting of doxylamine 12.5 mg taken twice daily with pyridoxine 25 mg taken qid. Although available OTC, Medicaid provides coverage for both of these products, therefore this trial must be verifiable by review of pharmacy claims or purchase history.~~

~~Initial approval of Diclegis will be for seven (7) days at a dose of up to four (4) tablets daily.~~

~~Additional therapy shall only be authorized with documentation that the member has experienced satisfactory efficacy within the initial approval period. Clinical studies have shown that efficacy of Diclegis should be assessable in most patients within 4 days, therefore extensions will not be granted if the patient has not experienced relief within the initial prior authorization period.~~

~~Non-preferred agents will only be approved on appeal~~.

Proposed criteria for subclass:

Non-preferred agents may only be approved after a trial and failure of a preferred agent unless one (1) of the exceptions on the PA form is present.

denotes change in current criteria
denotes new criteria

Zavzpret

Current criteria:

Zavzpret may be authorized after a trial and failure of two (2) chemically distinct preferred triptans, unless contraindicated. One of the trials must include sumatriptan nasal spray.

Proposed criteria:

Zavzpret may be authorized after a trial and failure of a preferred CGRP agent used for acute treatment **AND** a trial and failure of two (2) chemically distinct preferred triptans, including sumatriptan nasal spray (unless contraindicated).

denotes change in current criteria
denotes new criteria

Norvir powder pack

Norvir powder pack may be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia.

denotes change in current criteria
denotes new criteria

Inpefa

Inpefa may be authorized for an FDA approved indication **AND** clinical reasoning must be provided as to why the medical need cannot be met with a preferred SGLT2 agent.

denotes change in current criteria
denotes new criteria

Linzess 72 mg

Linzess 72mcg may only be approved for a diagnosis of chronic idiopathic constipation (CIC) AND for those who cannot tolerate the 145mcg dose. Linzess may also be approvable for a diagnosis of functional constipation for pediatric patients 6 to 17 years of age.

denotes change in current criteria
denotes new criteria

Sunosi

Current criteria:

Sunosi is approvable only with documentation of treatment failure after 30-day trials of both armodafinil and modafinil.

~~Sunosi is approvable only with documentation of treatment failure after 30-day trials of both armodafinil and modafinil~~.

Proposed criteria:

Sunosi may be authorized for adults 18 years of age and older with a documented FDA approved indication.

Prior authorization requests for Sunosi will be approved for Narcolepsy if the following criteria are met:

1) Patient is 18 years of age or older; **AND**

2) Completion of a sleep study and confirmed diagnosis of narcolepsy conducted by a physician who is a sleep specialist.

Prior authorization requests for Sunosi will be approved for Sleep Apnea/Hypopnea Syndrome if the following criteria are met:

1) Patient is 18 years of age or older; **AND**

2) Diagnosis of excessive sleepiness associated with obstructive sleep apnea or hypopnea syndrome, if

a. Patient has had a sleep study and diagnosis is confirmed by a sleep specialist physician; **AND**

b. Patient is compliant with Continuous Positive Airway Pressure (CPAP) or Bilevel Positive Airway Pressure (BiPAP) device and meets the criteria for Medicaid coverage of CPAP and/or BiPAP device; **AND**

c. Other medications used by the patient have been reviewed by the prescribing physician. Sedating medications should be discontinued if possible; **AND**

d. Score of at least ten (10) on the Epworth Daytime Sleepiness Scale.